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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,396	12/08/1998	JAN HOLGERSSON	45115-53906	3163

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/12/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/194,396

Applicant(s)

Holgersson et al.

Examiner

G.R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 26, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-19, 21-23, 25, 26, and 28-38 is/are pending in the application.
- 4a) Of the above, claim(s) 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-23, 25, 26, and 28-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. During a telephone conversation with Ivor Elrifi on 9/17/01, Applicant indicated that should a restriction election be required, Applicant would elect the Group comprising the fusion protein product. Affirmation of this election was requested in the last action, mailed 11/20/01. Applicant has failed to address the request. Affirmation of this election must be made by Applicant in replying to this Office action. Applicant is advised that failure to again confirm the election in response to this action will be considered non-responsive.

2. Claims 21-23, 25-26, and 28-38 are being acted upon.

3. In view of Applicant's amendment and response, filed 8/26/02, only the following rejections remain.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-26 and 28 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record as set forth in Paper No. 18, mailed 11/20/01. This is a new matter rejection.

Applicant's arguments, filed 8/26/02, have been fully considered but they are not persuasive. Applicant argues that Claim 25 has been canceled, however, the claim is still pending. Applicant argues that the experiment disclosed on page 12 of the specification supports the claim to the fusion protein of Claim 21, wherein the first polypeptide comprises more Gal α 1,3Gal epitopes than a wild-type P-selectin glycoprotein ligand-1. Said single experiment discloses a single construct that may have the claimed property, however, the claim recites a generic "first polypeptide" that cannot be supported by the single species disclosed in the example. Note that a genus may not support a subgenus even though there is a disclosed species within the genus and a subgenus is not necessarily described by a genus

encompassing it and a species upon which it reads, *In re Smith* 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b).

6. The following are New Grounds for Rejection necessitated by Applicant's amendment.

7. Claims 21-23, 25-26, and 28-38 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "the second polypeptide comprises an immunoglobulin heavy chain polypeptide." (Claim 21, 25, 26, and 29),

B) "wherein the first polypeptide comprises the extracellular portion of a P-selectin glycoprotein ligand-1 ..." (Claim 29),

C) "wherein the first polypeptide comprises more Gal α 1,3Gal epitopes than a wild-type P-selectin glycoprotein ligand-1." (Claim 33 and 38)

D) "wherein the first polypeptide comprises a part of a P-selectin glycoprotein ligand-1 that mediates binding to selectin ..." (Claim 34).

Applicant argues that support for a fusion protein comprising a heavy chain immunoglobulin can be found in the specification at page 5 in the recitation of "an immunoglobulin or [a] part thereof." Applicant is advised that a generic disclosure, i.e., a part of an immunoglobulin, is insufficient support for the recitation of a specific part, i.e., a heavy chain, see paragraph 5 above. Likewise, the single disclosure of the experiment on page 12 of the specification cannot support the generic recitations Claims 29, 33, and 38. Note that the recitation of a wild-type P-selectin glycoprotein ligand-1 in Claims 33 and 38 indicates that the claim is intended to be generic, i.e., more than one wild-type P-selectin glycoprotein ligand-1 exist. Regarding Claim 34, no support for the limitations of the claim have been indicated and none have been found in the specification.


8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
November 8, 2002


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600